REMARKS

Summary of the Office action

Claims 1-39 are pending. Claims 30-35 are withdrawn as being drawn to non-elected subject matter. Claims 1-29 and 36-39 have been examined. Claims 1-11, 19-29, and 29 stand rejected for obviousness-type double patenting in view of claims 1-24 and 35 of U.S. Patent 6,569,853 ("the '853 patent"). Claims 1-11 and 17-29 further stand rejected for obviousness-type double patenting in view of claims 1-13 of U.S. Patent 6,846,816 ("the '816 patent"). Claims 1-29 and 36-39 stand rejected for lack of enablement. Claims 12-16 stand rejected for indefiniteness. Claims 1-11, 17-29, and 36-39 stand rejected as being obvious over Dwivedi et al. (J. Pharmacol. Exp. Therapeutica, 291:688-704, 1999) in view of Makulu (Am. Soc. Pharmacol. Exp. Theraputics, 16:105, 1974) in further view of Windholz et al. (The Merck Index (1983) Tenth Edition, page 183, abstract 1308). Applicants address each of these rejections in turn below.

Rejections under the judicially created doctrine of obviousness-type double patenting

Claims 1-11, 19-29, and 29 are rejected for obviousness-type double patenting in view of claims 1-24 and 35 of the '853 patent. Claims 1-11 and 17-29 further are rejected for obviousness-type double patenting in view of claims 1-13 of the '816 patent. According to the Office, "the claims of the present application are generic to all that is recited" in the '853 and '816 patents. Applicants have addressed this rejection by cancellation of claims 1, 3, 4, 27, and 35, and amendment of claim 6, 7, 10, and 28. The claims as amended now

have no overlap with any of the claims of either the '853 patent or the '816 patent. Applicants draw the Office's attention to claim 2, which the Office incorrectly surmised was generic to the claims of '853 and '816 patents. In fact, there was (and is) no overlap between this claim and the claims of '853 and '816 patents. Accordingly, the rejection of the claims for obviousness-type double patenting may be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1-29 and 36-39 are rejected for lack of enablement. According to the Office, the specification does not enable the use of any compound of formula (I) in combination with any compound of formula (II) to treat any neoplasm. Applicants respectfully traverse this rejection as it applies to the amended claims.

In concluding that the claims lack enablement, the Office contends that the invention "is unpredictable unless experimentation is shown for the other compositions comprising other compounds of formula (I) and other compounds of formula (II)...to treat types of neoplasms." The Office provides no technical basis for this broad conclusary statement.

In order to make a rejection for lack of enablement, the Office has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). A specification disclosure that contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with

the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. As stated by the court, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

According to *In re Bowen*, 492 F.2d 859, 862-63, 181 USPQ 48, 51 (CCPA 1974), the minimal requirement is for the Office to give reasons for the uncertainty of the enablement. In the present case, the only reasons provided are that (i) the claims are broad; and (ii) there are no working examples. Neither of these reasons provides any basis for doubting the truth or accuracy of applicants' statements. The M.P.E.P. is clear that "the examiner should specifically identify what information is missing and why one skilled in the art could not supply the information without undue experimentation. See MPEP § 2164.06(a). References should be supplied if possible to support a *prima facie* case of lack of enablement, but are not always required. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). However, specific technical reasons are always required."

Notwithstanding the Office's failure to meet its burden, applicants submit that the claims are enabled. The proper test of enablement is "whether one reasonably skilled in the

art could make or use the invention from the disclosures in the patent coupled with the information known in the art without undue experimentation." *Hybritech, Inc. v. Monoclonal Antibodies, Inc.* 802 F.2d. 1318 (Fed. Cir. 1985). In analyzing what constitutes undue experimentation, the MPEP (2164.06) cites *In re Wands*, (858 F.2d 731, 8 USPQ2d 1400 (Fed Cir. 1988)):

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. (emphasis added)

The present situation is, in all important aspects, indistinguishable from the facts in *Wands* in which the Federal Circuit held that the applicant's claim was enabled, despite the necessity for screening a number of monoclonal antibodies, because the process of screening for antibodies that successfully bound antigen was straightforward. It follows that the present claims are also enabled, even if some screening would be necessary to identify the particular combinations of compounds of formulas (I) and (II) sufficient to treat various neoplasms.

At the time of filing, a skilled artisan, using no more than routine experimentation and the teachings of the present specification, could easily screen drug combinations to identify those that treat neoplasms. Such screening could easily be accomplished using standard techniques and thus does not constitute undue experimentation. Thus, the enablement rejection should be withdrawn.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 12-16 are rejected for indefiniteness because the phrase "an additional treatment of cancer" in claim 12 is allegedly vague. Applicants have addressed this rejection by amendment of claim 12, and this rejection may now be withdrawn.

Rejections under 35 U.S.C. § 103(a)

Claims 1-11, 17-29, and 36-39 stand rejected as being obvious over Dwivedi in view of Makulu, in further view of Windholz et al. According to the Office, it would have been obvious to combine Dwivedi's chlorpromazine with Makulu's pentamidine to treat cancer because each was known to have antineoplastic activities. The Office further alleges that the inclusion of a chemotherapeutic agent (as is recited in rejected claim 12 and claims dependent therefrom) would have been obvious over Dwivedi and Makulu in view of Windholz, which teaches treating cancer with a chemotherapeutic agent. Without assenting to the Office's position, applicants note that none of the claims now encompass the combination of chlorpromazine and pentamidine: independent claims 10 and 28 have been amended to no longer embrace pentamidine, while claim 2, the other remaining independent claim, did not embrace pentamidine in the first place. Additionally, there is nothing in any of the cited references that would have led one to the recited combinations. In view of the foregoing, this rejection may now be withdrawn.

CONCLUSION

Applicants submit that the claims are now in condition for allowance and such action is respectfully requested. Enclosed is a Petition to extend the period for replying to the Office action for three months, to and including August 9, 2005, and a check in payment of the required extension fee. If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: Aug. 9, 2005

Paul T. Clark
Reg. No. 30,162